



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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MAR 18 2002

Priscilla MacLean
Product Development Manager
Hercon Environmental
Aberdeen Road, P.O. Box 435
Emigsville, PA 17318-0435

Subject: Hercon Mosquito Attractant Emitter Strip Increase in Active Ingredient to 1660 mg of a.i. (octenol); Child Resistant Packaging (CRP) Testing; Label Amendments; EPA Reg. No. 8730-62;

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Dear Ms. MacLean :

This communication addresses a number of items, including:

- A) September 14, 2001 letter with request to waive the CRP related crush and bite tests for the Hercon octenol emitter end-use product.
B) Review of your data package (MRID 455608-01): Evaluation of the Hercon Mosquito Attractant Dispenser for Octenol Solubility; received by the Agency on December 10, 2001 (Amendment date: October 5, 2001).
C) Amendment dated January 22, 2001 for a change in packaging. Hercon proposed using the current fiberboard package with identical labeling, but to include two emitter devices in place of the single emitter. This "Two Pack" would double the amount of active ingredient from 150 to 300 mg. Additional questions concerning the proposed packaging were also received by your letter dated May 9, 2001.
D) May 30, 2001 letter requesting change in signal word from 'Warning' to 'Caution' and submission of product labels for the Hercon Mosquito Attractant Emitter Strip with 150 mg and another label for an emitter with 1660 mg active ingredient.

D) August 22, 2001 letter with enclosures (prototype emitter device and illustrations of 'bug zapper trap')

Table with 8 columns and 3 rows. Headers: SYMBOL, SURNAME, DATE. Row 1: 7511C, Peter, 2/28/02. Row 2: (blank). Row 3: (blank).

§
E) Master label for the 150 and 1660 mg emitter strips.

The Agency provides the following to address the above stated issues:

1) Concerning CRP Crush and Bite Tests (for emitter strips containing either 150 mg or 1.66 gram of octenol):

Your request and a letter from the independent laboratory concerning a waiver for the crush and bite test was reviewed and the waiver is granted. The Agency has made this decision based on the construction of your emitter and the amount of active ingredient you will be marketing in each emitter. The construction of the emitter is described in the enclosed copy of the Child Resistant Packing Review; dated February 7, 2002. The review notes the appearance of the prototype emitter provided to the Agency in August 2001 and furthermore documents the construction of the test emitters used in the Saliva Solubility Study.

This waiver is granted only for the emitter as tested. Should the shape, materials, or construction of the emitter change, the Agency may at its option require additional testing—including the crush and bite tests as well as additional saliva solubility tests.

2) CRP Saliva Solubility Test:

Enclosed you will find a copy of the Child Resistant Packing Review; dated February 7, 2002. As is stated in the report: "Less than 1% of a toxic amount (that is, of 3,876 mg 1-octen-3-ol for a 11.4 kg child) is available from the solubility tests (3 replicates). Therefore based on a worst case calculation this product does not meet the oral toxicity criterion for CRP based on an effective LD₅₀ of 0.34 g/kg."

Again, this testing is part of a 'case-by-case' basis and "... our determination in this case is product specific. Tests with other products may show different results and chemicals with different toxicological properties may be involved. Hence the margin of safety is product specific and is not applicable in a generic sense."

These findings indicate that the emitter strip does not require CRP and furthermore will allow you to change the signal word (as described below) on future packaging of the 150 and 1660 mg end-use product labeling.

3) Two Pack (with two 150 mg emitters enclosed in a single fiberboard package):

Based on the Saliva Solubility Study noted above, the Agency will accept your proposal to make 'Two Pack' promotional packages containing two emitters, each with 150 mg of octenol. Each emitter will be in a separate blister pack with the labeling information that you provided on the example pack supplied with the application dated January 22, 2001. Also refer to the Agency's August 31, 2001, letter in regard to labeling information on blister packs.

Note, however, the label must indicate the total amount of active ingredient in the promotional package. The net contents must also indicate two emitters. The statement "Equivalent to 150 mg..." in this case can be changed to "Each emitter is equivalent to 150 mg..."

You may wish to use the "Two Pack" label in subsequent years. This is permissible as long as the amount of active ingredient and formulation remain the same. Subsequent changes to the content and composition of the end-use product will require further review by the Agency. The Signal Word may also be changed on the "Two Pack" as described below.

Prior to production and sale of the two packs, submit three copies of the two-pack label for the Agency's review. The previous submission dated January 22, 2001, includes draft labels that presently do not fit the requirements as noted above.

4) Signal Word:

Based on the Saliva Solubility Study noted above, the Agency will review amendments for labeling (for the emitter with 150 and 1660 mg of octenol) with the Signal Word: Caution. As part of that amendment, please indicate that the laminate material used in the 150 mg octenol emitter is identical to that tested in the 1660 mg octenol emitter. This change in signal word will be acceptable only if you are using the same laminate. If the laminate composition changes, then the Agency will review how that change potentially impacts both CRP issues and labeling of new end-use products.

5) Placement of emitter in trap devices.

Your August 22, 2001 correspondence included questions about the manner in which the emitter is attached to the device.

Even with favorable ²the results from CRP testing, the Agency recommends placing octenol lures or emitters within devices. This can be accomplished in any one of a number of ways. While we are not able to instruct you on how to do this, there are perhaps options available to you to provide a device that makes such an installation convenient for manufacturing and later the customer's use of the device. Installing the emitter within a compartment on the device increases the chance that an essentially unlabeled pesticidal device will be retained where it fulfills its intended purpose. This also reduces arbitrary removal of the octenol dispensing emitter and the potential unnecessary handling by children.

⁶ E) Master label for the 150 and 1660 mg emitter strips.

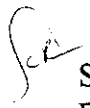
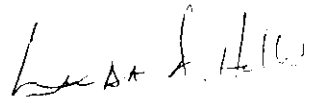
The 150 and 1660 mg emitters use the identical formulated laminate. Thus the CSF is identical for both emitters and the Agency recognizes the only difference in the emitters is the square inches (total area) of laminate used to create the smaller and larger amount

of active ingredient in each strip. As per our previous telephone communication, a master label can be prepared for the emitter strips. In this case the label will show all the language that is identical to all products and to also indicate the places where the sub-labels will display information unique to that label.

Submit three copies of the master label for the Agency's review.

If you have additional questions, please contact Dr. Todd Peterson at 703-308-7224.

Sincerely,



Sheryl Reilly, Ph.D., Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division

HERCON®
 MASTER LABEL
**MOSQUITO
 ATTRACTANT**

1-Octen-3-ol Emitter Strip (A)

or

1-Octen-3-ol Emitter Strip High Load (B)

For Use with Electronic Insect Killers and Traps

Increases the Device's Effectiveness
 in Killing Certain Mosquitoes and Biting Flies

Slow-Release Strip Designed to Emit
 Mosquito Attractant for 30 Days

ACTIVE INGREDIENTS:

1-Octen-3-ol 6.3 %*

OTHER INGREDIENTS 93.7 %

TOTAL 100.0 %

Equivalent to 150 mg 1-octen-3-ol per emitter strip ^(A) or
 1660 mg 1-octen-3-ol per high load strip. ^(B)

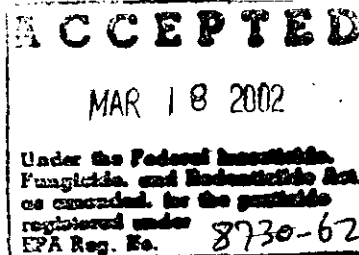
CONTENTS: 1 Attractant Emitter Strip ^(A) or
 1 High Load Attractant Emitter Strip ^(B)

MINIMUM NET WEIGHT: 0.08 oz (2.4 g)/Emitter strip or
 0.93 oz (26.35 g)/High Load Emitter strip

KEEP OUT OF REACH OF CHILDREN

C A U T I O N

Read Directions and Precautionary Statements Before Use



HERCON® MOSQUITO
 ATTRACTANT

1-Octen-3-ol Emitter Strip

or **1-Octen-3-ol Emitter Strip High Load**

For Use with Electronic Insect Killers and Traps

The Hercon Mosquito Attractant is intended for use as a lure with an electronic insect killer ("bug zapper") such as Stinger, and all other brands, or trap. It is designed to release 1-octen-3-ol, an insect attractant, continuously for 30 days. Trap or zapper effectiveness is increased by luring mosquitoes and biting flies to it.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed, absorbed through the skin or inhaled. Avoid contact with skin, eyes and mouth. Wash hands thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT

IF INHALED: Move to fresh air

IF ON SKIN: Wash affected areas with soap and water

IF IN EYES: Flush with plenty of water. Call a physician if irritation persists

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

When ready to use, remove mosquito attractant dispenser from pouch. Attach dispenser to outer enclosure by placing it in the appropriate attachment on the zapper. When used as trap lure, read attachment directions on trap label for best results. Replace attractant dispenser after 30 days.

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

PESICIDE STORAGE: Store in a cool dry place. Do not reuse empty pouch or dispenser.

PESTICIDE DISPOSAL: Wrap dispenser in paper and discard in trash.

Made in the USA by

HERCON
Environmental
 HERCON ENVIRONMENTAL

Emigsville, PA 17318-0435

EPA Reg. No. 8730-62

EPA Est. No. 8730-PA-01

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(A) **1-Octen-3-ol Emitter Strip**

(B) **1-Octen-3-ol Emitter Strip High Load**

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